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| EXAMINER | | | | |
| KIM, JENNIFER M | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1617 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/552,315

Applicant(s)

AKHAPKINA ET AL.

Examiner

JENNIFER M. KIM

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/27/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The response filed July 27, 2009 have been received and entered into the application.

Action Summary

The rejection of claim 2 under 35 U.S.C. 102(b) as being anticipated by INSTITUT MEDIKO-BIOLOGICHESKIKH PROBLEM et al. (RU 205051) of record is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claim 2 under 35 U.S.C. 102(b) as being anticipated by Applicants' admission is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable over Differding et al. (WO 01/62726A2) is being **maintained** for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed July 27, 2009 have been fully considered but they are not persuasive. Applicants essentially argue that the Differding patent does not include the compound, N-carbamoyl-methyl-4-phenyl-2-pyrrolidone in their examples as providing antidepressant activity; therefore, the patent does not include any evidences of antidepressant activity of the compound. This is not found to be persuasive because disclosed examples and preferred embodiments in the Differding reference do not constitute a teaching away from a broader disclosure or nonpreferred embodiments which disclose the treatment of depression with the compound N-carbamoyl-methyl-4-phenyl-2-pyrrolidone. **In re Susi, 169 USPQ 423 (CCPA 1971)**. In this case, Differding clearly names N-carbamoyl-methyl-4-phenyl-2-pyrrolidone (also known as (2-(2-oxo-4-phenyl-1-pyrrolidinyl) acetamide) as their compound 2 on page 67. Differding also teach that the compound having 2-oxo-1-pyrrolidine such as N-carbamoyl-methyl-4-phenyl-2-pyrrolidone is effective for the treatment of depression. This compound is encompassed by the generic structure of the 2-oxo-1-pyrrolidine compounds in Differding's claims 1 and 34. Accordingly, it would have been obvious to one of ordinary skill in the art to interchange one compound for another when specific compounds are taught as equivalents and the antidepressant utility is retained. Accordingly, the instant claim is obvious therefrom. Applicants argue that enclosed letter comprising declaration of unexpectedness of the result. The letter comprising declaration has been carefully reviewed and considered. The letter comprising declaration states that the antidepressant activity of N-carbamoyl-methyl-4-phenyl-2-pyrrolidone revealed by the

instant inventors was unexpected and the obtained results were remarkable discovery. However, this is not persuasive because the declaration still does not change the fact that the usefulness of the compound, N-carbamoyl-methyl-4-phenyl-2-pyrrolidone for the treatment of depression was earlier discovered and taught by the cited reference, Differding et al.

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by INSTITUT MEDIKO-BIOLOGICHESKIKH PROBLEM et al. (RU 205051) of record.

INSTITUT MEDIKO-BIOLOGICHESKIKH PROBLEM teaches the use of N-carbamoylmethyl-4-phenyl-2-pyrrolidone (carphedon, also known as phenotropyl) as an agent with nootropic activity. (see also international search report).

The limitation of "treatment of depression" is noted. However, where the claimed invention is a chemical compound, the "compound and all of its properties are inseparable; they are one and the same thing". In re Papesch, 315, F2d 381, 391 (C.C.P.A. 1963). In this case, the same active substance is taught by the reference.

Therefore, the same active substance taught by the reference would inherently have the properties of displaying antidepressant activity. The reference clearly anticipates the claimed substance. It discloses the same chemical compound. It must possess the same properties as claimed because it is one and the same compound.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Applicants' admission.

Applicants admit that phenotropyl (also known as N-carbamoylmethyl-4-phenyl-2-pyrrolidone) is known as a substance having nootropic activity taught in RU2050851. (see specification page 2, lines 9-12).

The limitation of "treatment of depression" is noted. However, where the claimed invention is a chemical compound, the "compound and all of its properties are inseparable; they are one and the same thing". In re Papesch, 315, F2d 381, 391 (C.C.P.A. 1963). In this case, the same active substance is taught by the reference. Therefore, the same active substance taught by the reference would inherently have the properties of displaying antidepressant activity. The reference clearly anticipates the claimed substance because it discloses the same chemical compound with properties inseparable as claimed from that compound.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(b).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Differding et al. (WO 01/62726A2) of record.

Differding et al. teach that 2-oxo-1-pyrrolidine derivatives of formula (I) including 2-(2-oxo-4-phenyl-pyrrolidinyl)acetamide (also known as N-carbamoylmethyl-4-phenyl-2-pyrrolidone set forth in claim 1) is useful for the treatment of depression. (page 67 compound 2, page 89 claims 1 and 33-36).

Differding et al. do not expressly exemplify the treatment of depression comprising administering N-carbamoylmethyl-4-phenyl-2-pyrrolidone set forth in claim 1.

It would have been obvious to one of ordinary skill in the art to employ any one of 2-oxo-1-pyrrolidine derivatives of formula (I) including N-carbamoylmethyl-4-phenyl-2-pyrrolidone set forth in claim 1 because Differding et al. teach that the 2-oxo-1-pyrrolidine derivatives of formula (I) including 2-(2-oxo-4-phenyl-pyrrolidinyl)acetamide (also known as N-carbamoylmethyl-4-phenyl-2-pyrrolidone is effective for the treatment of depression and because such derivatives are equivalents and the effectiveness of antidepressant activity is retained. One would have been motivated to make such modification in order to achieve an expected benefit of treating depression in a patient suffering from such disorder with N-carbamoylmethyl-4-phenyl-2-pyrrolidone taught to be effective in treating depressive disorder in view of Differding et al.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JENNIFER M. KIM** whose telephone number is

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(571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
September 29, 2009